

REMARKS

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the amendments and remarks herein. The Examiner is thanked for indicating that the rejections under 35 U.S.C. §103, involving Haanes in view of Cates and Haanes in view of Barbour, have been withdrawn.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 17-28 and 38-49 are pending in this application; claims 43-48 are amended. Support for intranasal administration of the claimed vaccines and compositions can be found in Example 17 on page 23 of the specification. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 17-32 and 38-49 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Haanes *et al.* (U.S. Patent No. 5,753,235 or 5,804,197), in view of Paoletti *et al.* (U.S. Patent No. 5,843,456). The rejection is traversed.

The claims are directed to a recombinant CHV comprising and expressing at least one heterologous nucleotide sequence encoding rabies virus G protein. As discussed in the Amendments filed on March 7, 2003 and July 15, 2003, the cited art does not teach or suggest a recombinant CHV comprising and expressing at least one heterologous nucleotide sequence encoding rabies virus G.

The Advisory Action alleges that “live recombinant vaccines are commonly thought to induce good immune responses because of the *in vivo* replication of the virus and the endogenous expression of the antigen coding sequences.” No evidence or support for this statement has been provided. Conversely, Applicants have provided evidence demonstrating the efficacy and superiority of the claimed invention. Xuan *et al.* shows that the antibody titers are higher using a recombinant CHV containing the nucleic acid sequence encoding rabies virus G protein than those elicited by a commercial vaccine containing inactivated rabies virus.

Therefore, not only is the instant invention unexpectedly successful, it also shows surprisingly superior results over classical vaccines. In addition, claims 43-48 have been amended to recite intranasal administration, as was demonstrated to be effective by Xuan *et al.* Claim 49 has not been amended as such because it does not require administering the virus to a subject.

Furthermore, Applicants have submitted evidence that immunization with different recombinant viral vaccines does not produce analogous results. Gilbert *et al.* describes a recombinant vaccinia virus vector containing the *env* gene of feline leukemia virus (FeLV), encoding the gp70 protein. Although the gene was expressed in vaccinated cats and mice, no anti-gp70 antibodies were detected in the serum of vaccinated animals, indicating a clear lack of immunogenicity. In contrast, Wardley *et al.* demonstrates a decisive protective immunogenic response against FeLV using a recombinant herpesvirus vector containing the FeLV *env* gene. This directly supports the argument that poxviruses and herpesviruses are not analogous vaccine vectors, as they produce disparate results using the same immunogen, *i.e.* the herpesvirus-based vaccine elicited a protective immune response, while the poxvirus-based vaccine did not. These studies are evidence in support of Applicants' position that one cannot extrapolate from one viral vector system to another with an expectation of success. The Examiner is respectfully reminded that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). Therefore, Paoletti cannot be properly combined with Haanes as the basis for an obviousness rejection, as no reasonable prediction of success can be drawn from the cited art.

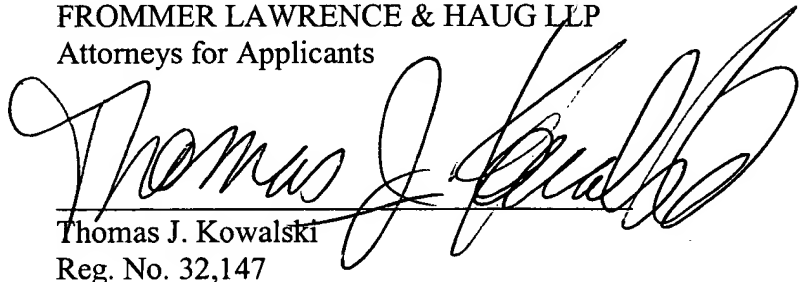
Accordingly, the instant invention is not *prima facie* obvious. The cited references, alone or in combination, do not teach or suggest the desirability and efficacy of a recombinant CHV comprising and expressing at least one heterologous nucleotide sequence encoding rabies virus G antigen. Therefore, reconsideration and withdrawal of the rejections under §103(a) are requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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A large, stylized handwritten signature in black ink, appearing to read "Thomas J. Kowalski", is written over a horizontal line.

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